

Woodford Submission to the Slorach Review of NZFSA Processes. February 2008.

Submission to:

Review of NZFSA's Risk Management Framework for Making Decisions on Consumer Protection, and with Particular Reference to Issues of A1 and A2 milk

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For the Attention of : Dr Stuart Slorach

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Introduction

The purpose of this submission is to bring to the attention of Dr Slorach, as the appointed reviewer, various issues associated with the way in which NZFSA has dealt with the issue of A1 and A2 milk.

This submission needs to be read and considered in conjunction with two other sets of material. The first is the book 'Devil in the Milk' which I authored and which was published in September 2007 (Craig Potton Publishing). The second is the 17 page working document dated 7 October 2007, authored by me and analysing the behaviours of NZFSA in relation to the release of the Swinburn Report, and already supplied to Dr Slorach on 23 January 2008. That October 2007 document, which is titled 'The Role of the NZFSA in Investigating Health Issues Concerning A1 and A2 Milk', is based on NZFSA correspondence obtained from the NZFSA under the Official Information Act.

In writing this current document I have been conscious of not unnecessarily repeating material already presented in either the book or the October 2007 document. Accordingly, I emphasise the importance of taking those materials fully into account.

In writing this current document I am also influenced by the discussions held between Dr Slorach and myself on 23 January 2007. In particular, there were perspectives presented by Dr Slorach in those discussions which seem to require a response.

I recognise that those 23 January discussions were held at an early stage of the review before Dr Slorach had a full opportunity to assess all of the information. However, I do express concern at the apparent role being played by NZFSA within this review, and of the influence NZFSA can bring to bear, given that NZFSA is itself the subject of the review. I am particularly aware of the opportunities that NZFSA has to present its slant on events. Given the NZFSA track history in regard to the A1/A2 saga, I therefore suggest to Dr Slorach that he is cautious of accepting NZFSA perspectives without external corroboration that he has indeed been supplied with all relevant information.

During our January discussions, it became apparent that NZFSA had not supplied Dr Slorach with my document of 7 October 2007. Dr Slorach sought confirmation that NZFSA had indeed received this document which was sent to the Minister on 7 October (and also to selected media) and we had some conversation around that. In confirmation, I now note that the document did indeed reach NZFSA, either directly or indirectly, given that NZFSA in their press release of 8 October made explicit reference to this document and alleged flaws within it. I make these points simply to clarify that NZFSA have had access to this document. I have no particular interest in pursuing further whether NZFSA did or did not supply these materials to Dr Slorach as part of the review materials.

Finally in relation to this introduction, and as a consequence of an element within our conversation of 23 January, I draw Dr Slorach's attention to the final paragraph on p13 in the introduction to my book about academic freedom and how academics represent themselves and not their university. It would be very unusual for a NZ university to have a formal position on a matter such as A1 beta casein and my university has no such

position. What I write, both then and now, is on behalf of myself as an academic within the Agriculture and Life Sciences Division of Lincoln University.

The focus of the Swinburn Review

The initial decision in 2003 to appoint an independent consultant to review safety issues associated with A1 and A2 beta-casein was a decision made by the NZFSA itself. Whether or not NZFSA was the most appropriate agency to undertake such a review might be debated. I do not choose to debate that point. However, I do make the point very strongly that having decided to undertake such a review then the agency had very clear responsibilities to do so in a manner that was objective and totally independent of any existing stance in relation to milk nutrition. They also had a responsibility to then communicate Professor Swinburn's review accurately to the public. They also had a responsibility to communicate the findings to other relevant government agencies, given that no other government agency would be likely, in the circumstances, to undertake its own review in relation to these issues.

A key starting point is to note that the 2003 Swinburn review (which, following review was released in August 2004) was titled 'Beta-casein A1 and A2 in milk and human health'. The terms of reference were headed : 'Review of research relevant to A1/A2 milk', and included the requirement to 'evaluate the implications of such research'. *It was not a review of whether or not milk is nutritious.*

If it had been a review of whether or not milk is nutritious then it would have required a totally different set of terms of reference to those that were supplied. The responsibility of NZFSA was therefore to communicate the findings of the report in relation to the risk factors relating to A1 and A2 beta-casein.

It is relevant to note here that to the best of my knowledge no-one associated with the A1 and A2 debate has ever questioned whether or not milk is nutritious. Indeed it can be taken as a clear starting point that milk contains many nutritious elements. The question therefore is not whether or not milk is nutritious, but whether or not there are specific risk factors relating to A1 beta-casein which is present in the milk of some cows. These points are of particular relevance to term of reference (v) of the Slorach Review.

The existing stance of NZFSA

It is very clear that NZFSA had an existing stance in relation to milk being nutritious and an important component of the diet. It is also very clear that NZFSA perceived that the issue of A1 beta-casein posed a threat to that stance. This perception may have been linked to misunderstanding both as to the existing number of pure A2 cows available in NZ (more than 1,000,000, with no more than 10% of these required to supply the total fresh milk requirements of all New Zealanders) and also in relation to the practicality of converting the rest of the NZ herd to A2. In regard to this issue of conversion, I draw attention to a statement from LIC, the dominant supplier of dairy semen to the NZ dairy industry, on p23 of their industry publication of "Your Choice" of Spring 2007.

"LIC could, within 48 hours, respond to a market directive to move to A2 milk (i.e. only put A2 bulls forward for collection). This would mean that, within eight to ten

years, virtually every cow in New Zealand would be A2. This shift – if directed by consumer demand – could be done without compromising other genetic qualities.”

Regardless of why NZFSA had such a stance in relation to milk, there is no doubt from its own documentation that it did have such a stance. This is not simply a matter of interpretation. NZFSA has itself been explicit that it had and has a stance.

This raises the generic issue of whether or not there is potential conflict within the NZFSA charter to ‘protect and promote public health’. Having a requirement to ‘promote’ public health leads inevitably to having a stance on a range of matters. A potential problem then arises when that stance descends into naivety such as saying that ‘milk is safe’. The reality, of course, is that it is difficult to name a single food product which is safe for all people in all circumstances and in all quantities. The potential problem then becomes a very real problem when specific events and findings challenge the accuracy of these naïve statements.

There are two possible responses in dealing with the above problem. The first is to separate the role of ‘protecting’ from that of ‘promoting’ public health. There would indeed seem to be a tenable argument that the Ministry of Health is the best placed institution within NZ to undertake promotion of nutritional behavioural aspects of public health. That would then leave NZFSA with the role of protection, which they could then do uncluttered from the need to have public health stances related to nutritional behaviour. Alternatively, if the ‘protect and promote’ functions are to stay within the same agency then there is a clear need for higher standards of training within NZFSA as to how to deal with the potential for conflicts within these roles. I make no suggestion as to which of these paths should be followed. But I do say very clearly that NZFSA has shown itself as currently lacking the necessary skills to manage its existing charter.

The Swinburn message

The key message from Professor Swinburn was one of ‘uncertainty’. He identified a lot of evidence but he did not find, in his opinion, that there was proof.

Professor Swinburn did not say anywhere in his report that ‘milk was safe’. He has subsequently stated in the media that this decision not to state that ‘milk was safe’ was purposeful.

Professor Swinburn also said in his report that more research was needed. He reinforced this message several times, including stating (p6) that ‘the appropriate government agencies have several important responsibilities’ relating both to further research and communicating the current state of knowledge.

Given a report of more than 40 pages there is considerable scope for taking messages out of context. I therefore chose in my book to quote the last three paragraphs of the Lay Summary. I did this because it provides a linked series of statements, which by definition reduces the potential of changing an author’s message through use of non sequential statements. Also, my choice was influenced by the logic that the concluding statements

that an author makes can indeed be assumed to be important statements of conclusion. I regard these paragraphs as sufficiently important that I repeat these three paragraphs here.

The A1/A2 hypothesis is both intriguing and potentially very important for population health if it is proved correct. It should be taken seriously and further research is needed. In addition, the appropriate government agencies have a responsibility to communicate the current state of evidence to the public, including the uncertainty about the evidence. Further public health actions such as changing dietary advice or requiring labelling of milk products, are not considered to be warranted at this stage. Monitoring is also required to ensure that any claims made for A2 milk fall within the regulations for food claims.

Changing the dairy herds to more A2 producing cows is an option for the dairy and associated industries and these decisions will undoubtedly be made on a commercial basis. Changing dairy herds to more A2 producing cows may significantly improve public health, if the A1/A2 hypothesis is proved correct, and it is highly unlikely to do harm.

As a matter of individual choice, people may wish to reduce or remove A1 beta-casein from their diet (or their children's diet) as a precautionary measure. This may be particularly relevant for those individuals who have or are at risk of the diseases mentioned (Type 1 diabetes, coronary heart disease, autism and schizophrenia). However, they should do so knowing that there is substantial uncertainty about the benefits of such an approach.

Descending the slippery path.

The key NZFSA message in releasing the Swinburn report was that all milk was safe. The opening statement in their press release (dated 3 August 2004) was:

Consumers are advised to keep drinking milk as a nutritious food, no matter whether it's A1 or A2, as there is no food safety issue with either type of milk.

It was this simple and clearly inaccurate message that the majority of media picked up as their headline message. A few media, but only a few, presented a message that more accurately reflected the tenor of Swinburn's report. However, to do this they had to go past the NZFSA press release and read the report in some detail as the Lay Summary was not included in the released materials.

I note that in our discussions of 23 January Dr Slorach put forward a suggestion, which NZFSA have themselves put forward, that the omission of the Lay Report did not result in the non release of any information. This argument goes along the lines that a Lay Summary cannot include information that was not in the main report (including the Executive Summary). At one level that is true, but what a Lay Summary does is bring together in clear non technical language the key messages.

Those of us (including NZFSA Communications staff) who work with the media understand very clearly the importance of the 15 second sound bite and its print media equivalent. That 30 word opening statement from NZFSA was the key statement which captured the message that the general public received.

The key issue with the omission of the Lay Summary is therefore not that it precluded access to information by those who wished to seek out that information in some detail. But its absence made it much harder for those who wished to point out to the general public the fundamental differences between the message of the Swinburn Report (one of uncertainty) to that of the NZFSA ('no food safety issue').

The reality is that most media relied on the 307 word NZFSA press release (or elements thereof), the tone of which was set by its 30 word opening statement. If the media had access to the 499 word Lay Summary, then those who accessed this Summary would have immediately recognised the incongruity between what Swinburn said and what the NZFSA portrayed him to have said. In particular, the 225 word concluding statement from this Lay Summary provided succinct evidence that the NZFSA interpretation was false. Of course the media did have the opportunity to read the full report, and within that they would have found a 919 word Executive Summary that set out the key findings, although much less succinctly, and less starkly from the perspective of the general public than in the Lay Summary. However, the reality is that most media did not do that, and those of us with media and communications experience would have predicted that in advance.

I note that the question of the Lay Summary receives explicit mention in the terms of reference for the review being undertaken by Dr Slorach. I will therefore make some further comments about the initial non release of the Lay Summary in this submission, but without going into all of the detail set out in my October 2007 document. But before doing so I wish to emphasise that the issue of the Lay Summary must not be considered in isolation. It was simply one element of the communication strategy in relation to release of the report.

One element of that strategy goes right back to the initial advice to Professor Swinburn by NZFSA's Carole Inkster that: *'In relation to discussion of the precautionary principle our preference would be to not discuss it as the precautionary principle – this term has all sorts of baggage associated with it (especially European baggage).'*

Subsequently there was confusion around the decision to release the report at a time when Professor Swinburn was unavailable to comment. NZFSA apologised to Professor Swinburn for this decision, saying that it was based on a misreading of a message from Swinburn. But they were aware of this mistake prior to the actual release. They decided not to put back the release date a few days (which would seem inconsequential relative to the more than 12 month delay since Swinburn had initially delivered his report). And Carole Inkster on behalf of NZFSA then opined in an email to Professor Swinburn

‘we did not believe that [your unavailability] was a distraction in so far as the media were not able to engage on points of science unnecessarily and potentially beat up the issue’

This is an absolutely amazing statement which tells a remarkable story as to the arrogance of the NZFSA.

A key issue in relation to the release of the Swinburn review is that NZFSA portrayed the outcomes in manner that involved ‘spin’. I use that word purposefully given that it is the word that Professor Swinburn himself used when writing to NZFSA expressing disappointment at the way they had released his report. One could use stronger words.

The fact that Professor Swinburn wrote to NZFSA, subsequent to the release of the report, and characterising their actions in this way, clearly gave NZFSA an opportunity to re-assess their position. They chose not to do so. Indeed those subsequent comments of Professor Swinburn would not have come into the public arena if it were not for my obtaining them through an Official Information Act disclosure.

In correspondence to NZFSA following the release of the report, Professor Swinburn also made his position very plain once again in regard to the uncertainty, and in language that could not be misconstrued, by using the illustration that if he were the parent of a diabetic child, and was becoming the parent of another child, then he would wish to use A2 milk based on the potential benefit in relation to the potential cost. Such a statement cannot be reconciled with the NZFSA position that there is ‘no food safety issue’.

I will now return briefly to the issue of the release of the Lay Summary, but emphasising once again that this issue must be considered in the overall context of NZFSA’s behaviours in relation to the Swinburn Report. In particular, if the NZFSA had put out an accurate press release then the implications of omitting the Lay Summary would have been less.

NZFSA’s Carol Barnao, wrote to me on behalf of NZFSA on 12 August 2004 when NZFSA released the Lay Summary to me under the Official Information Act. She stated that the Lay Summary was not included *“as we feel that the tone is inconsistent with the main report.”*

This is one of several reasons that NZFSA has given for not releasing the Lay Summary at that time. Others have included (from Carole Inkster on Radio NZ) that it was not released because it was not part of the contract. (However, NZFSA records - which I hold having been obtained under the Official Information Act - show that one of the reviewers had specifically requested that such a Lay Summary be included, and Professor Swinburn wrote the Lay Summary in response to that request). Another public response has been that it was not necessary as people could read the full report. (This required a judgement from NZFSA that the peer reviewer was wrong in requesting this). Yet another response from Carole Inkster to the media has been that NZFSA can do what it likes in regard to what it does and does not release.

I am inclined to the view that Carol Barnao's response was indeed honest. One does not make up a statement like that from nowhere. What it shows is that NZFSA was indeed making its own judgements (either with or without external influence from elsewhere) as to what should be made available to the public. The other explanations were made in a futile attempt to cover the tracks. Of course if there were a perceived difference in tone between the Lay Summary and the main report, and the NZFSA thought the difference was serious, then NZFSA should have gone back to Professor Swinburn and sought clarification and confirmation that the written words in each case did indeed truly represent his position.

I note that the NZFSA points out (and does so repeatedly) that the Lay Summary is now available on their website. This is correct. But it only went up there once I had gained public release through the Official Information Act, and following several refusals to release it. By then the damage had been done. And NZFSA still continues to publicly assert that there is no food safety issue and fails to acknowledge that its message is at odds with Professor Swinburn's Report.

Process flaws relating to the Swinburn Review and its terms of reference

The terms of reference (TOR) for the Swinburn review were flawed. It is not explicit from the Swinburn TOR as to whether or not the science relating to beta casein, and particularly the peptide beta-casomorphin⁷, were to be part of the review.

My own interpretation is that they should have been assumed to be included within the stated TOR. However, it is clear from perusal of correspondence between Professor Swinburn and NZFSA that there was agreement that they were not to be included. This was a huge flaw of process, and NZFSA must bear a large part of the responsibility. It meant that the relevant biochemistry and pharmacology were totally ignored. However, it is this pharmacology and biochemistry, both *in vitro* and *in vivo*, that provides fundamental understanding. Perusal of the correspondence shows that NZFSA was alerted to the importance of the underlying science by A2 Corporation, and this occurred while Professor Swinburn was at an early stage of his review. Whether or not this was communicated to Professor Swinburn is unclear (but the supposedly complete record of correspondence supplied under the OIA includes nothing to this effect). What is clear is that Professor Swinburn made it clear to NZFSA as to the approach that he was taking, and that NZFSA was satisfied with this approach.

It is widely understood that major illnesses with which A1 beta-casein is implicated are auto-immune in character and tend to have long latency periods. Conducting clinical trials for such diseases is highly problematic. To use just one comparable example for a long latency disease, if we insisted on double blind clinical trials as the only method of showing that smoking causes cancer, then we would still be saying that the relationship between smoking and cancer is inconclusive. It is often only by combining epidemiology with underlying science and animal trials that the causation can be 'proven' as that term is usually understood.

I note that the Swinburn TOR are dated March 2003 on the NZFSA website. However, NZFSA correspondence shows that NZFSA were indeed fine tuning the TOR well beyond this date, and that Professor Swinburn's contract was not finalised for several months thereafter. Therefore there is no reason why the underlying science could not have been included.

NZFSA's actions in the period following 13 September 2007

The TOR for Dr Slorach's review do not explicitly include the ongoing actions of NZFSA since the release of my book in September 2007. However, TOR (vi) relates to issues of transparency and communication of decisions in regard to A1 and A2 milk. Although this TOR has a qualification in regard to 'in particular', it is important that this is not interpreted as 'exclusively'. The issues that I am about to refer to do indeed therefore fit very clearly under the criteria of ongoing communication in relation to A1 and A2 milk.

NZFSA has chosen to continue to attack any suggestions that A1 beta-casein is relevant to human health. For example, on 13 September 2007 NZFSA released a press release denigrating my book, but had to then admit to the media that NZFSA had not at that time sighted the book. (It was not in general circulation until the following day). Right from that date its officers have asserted that I have brought forward no new science. This is despite the fact that my book draws on more than 30 peer reviewed papers published in 2004 and thereafter. (None of Swinburn's references are dated later than 2003, and some of the 2003 papers discussed in my book would also not have been available at the time Swinburn's review was submitted for peer review.) In all, Professor Swinburn references 38 research publications whereas in my book I present information from well over 100.

In fact there are three 2007 NZFSA press releases on the NZFSA website (13 September, 24 September and 8 October) that attempt to denigrate the evidence I have brought forward, and which do so by attacks that both misconstrue my position and also focus on attacking my credibility rather than debating the evidence. This is unacceptable behaviour.

In fact the NZFSA was given the opportunity to debate the evidence with me at a forum in Wellington organised by the NZ Royal Society in conjunction with New Zealand's National Museum, Te Papa, as part of their Science Direct program. NZFSA officers were unwilling to engage in debate, and it has been suggested to me by Dr Slorach that perhaps this was because they are not experts in the science. Fair enough. But if they lack the expertise to debate the science, then they also lack the expertise to make the denigrating comments via their website.

Returning to these press releases (which remain on the website), the 13 September press release restates the false messages of the previous NZFSA press release of August 2004. The 13 September press release also states that "*we are not aware of any new research from anywhere in the world*". The most favourable judgement that one can put on such a statement is that it is made from a state of total ignorance.

Carole Inkster also stated on TV1 on 14 September that if there had been more research then Professor Swinburn would have informed the NZFSA. This was a nonsense, given that Professor Swinburn had no ongoing relationship with NZFSA in relation to A1/A2, and had, as he had informed me just days previously, not been working in this field since the time of his review more than three years previously. To tell untruths such as this is totally unprofessional.

I could go on (and on!) describing the way that NZFSA has continued to reinforce its existing position, and to attack my position by misrepresenting that position. But instead I will quote briefly from the NZFSA website (last accessed 3 February 2008) which states in the lead in statement to the A1/A2 section:

“There is insufficient evidence to suggest any link between milk protein consumption and heart disease and insulin-dependent diabetes.”

If this statement is correct then NZFSA might like to explain why the International Diabetes Federation has invited me to present a plenary paper, organised as a public forum, at their forthcoming Western Pacific Congress. (And I have other invitations from scientific organisations to present papers at their conferences.) Would this be occurring if there was no merit in the information I have been putting forth? Quite simply, NZFSA loses all credibility by continuing to take such an extreme position as that the evidence is insufficient to even ‘suggest’ a link.

Industry relationships

In my document of 7 October 2007 I laid out the issues of NZFSA having strong but informal links with particular sections of industry, and the dangers and inherent uneven handedness associated with this. I will not traverse the same ground here. However, I will refer to one recent example which occurred at the time of announcing the Slorach Review, which suggests that NZFSA continues to be influenced, either knowingly or unknowingly, by groups that are less than independent.

At that time (early to mid October 2007) NZFSA Director Dr McKenzie made a number of comments to media along the lines of ‘burying the issue once and for all’ through the proposed review. It was notable that his major concern seemed to be with maintaining the public credibility of his organisation rather than dealing with NZFSA’s failings in an objective manner. As part of that ongoing attempt to defend NZFSA’s position, and to buttress his own position, he referred to a review paper by Professor Truswell which he said he happened to have on his desk. Exactly how Dr McKenzie’s attention happened to have been drawn to this particular partisan paper is unclear, but there are essentially two alternatives. The first is that he had read my book, in which case he would have known that Professor Truswell was closely associated with Fonterra as a consultant on A1/A2. Indeed Professor Truswell has now admitted himself (Dairy Exporter of Dec 2007) that he was a paid consultant for Fonterra in relation to providing advice on the A1/A2 issue. Dr McKenzie would also have known from my book that Truswell was a witness for Fonterra in its unsuccessful attempt to challenge an A2 Corporation patent. To have singled out this one paper in the knowledge of those circumstances would have been highly inappropriate. The other alternative is that Dr McKenzie had not read my book and the evidence therein, nor indeed conducted his own review of the literature which

would have informed him that this was a partisan and discredited paper. If this were the case then it can only be that partisan industry-related sources had 'fed' this particular paper to Dr McKenzie without Dr McKenzie knowing that he was being manipulated. Either way, this incident does not reflect well on the NZFSA and its relationships with industry.

The key issue is that this specific example, plus many outlined in my document of 7 October 2007, are all part of a consistent pattern of unprofessional behaviour that places defence of an existing stance above objective analysis and communication.

The defence that NZFSA's position is consistent with other international food safety and health organisations

The reality is that to date the issue of A1/A2 milk has not been considered by other international authorities. The reason that this issue has come to the fore within New Zealand before other countries is that much of the key research has taken place in New Zealand. It is also in New Zealand that one group of commercial interests have sought to capitalise on this research, and another group have sought to denigrate it. This has included false statements and non disclosure of key research data as outlined in my book, and at least one partisan paper written by an individual who had relevant non disclosed industry associations. The stance of NZFSA has itself contributed to the challenges of getting these issues debated objectively on the international stage.

Moving forward

In essence there are two options.

Option 1 is that NZFSA continues to deny the findings of their own reviewer, Professor Swinburn, and continue to deny that there have been significant flaws in the way they have implemented their own risk management procedures. If they persist in going down that track then they will simply bury themselves (and not just 'bury the issue' as their CEO stated in the media). Quite simply for the sake of their own credibility they have to admit to their shortcomings.

Option 2 is therefore to admit that mistakes have been made, show that NZFSA is a learning organisation, and move forward. If this is to occur then at the very least there is a need for enhanced training programs within NZFSA to better equip NZFSA staff to deal with the complexities of food safety issues and the uncertainties that surround these issues. In particular, the NZFSA personnel need considerable training in how to deal with matters of non certainty and the precautionary principle. They need to learn that giving messages of certainty where no such certainty exists is a recipe for organisational disaster. They have to learn to be transparent in advising consumers of the state of knowledge (as in this case determined by their own reviewer) and including the uncertainties. And they need to learn how to engage in constructive debate. Organisationally, they need to reflect on the dangers of organisational spin and organisational public relations that involves massaging of situations. Not only scientists, but bureaucrats working in scientific organisations (such as NZFSA) need to understand the principles of scientific integrity. This includes remaining open to the possibility that

existing stances need modification. Indeed a scientist who loses the scepticism to regularly reassess his or her own position, and to act accordingly, is no longer a scientist.

It is also apparent that NZFSA need training in how to deal with commercial interests in a way that is proper and balanced. It is highly inappropriate for NZFSA to be dealing informally with some groups in industry and formally with other groups. In particular, given the situation in NZFSA where some personnel are former industry employees, there is a need for specific training as to how former allegiances and relationships with former industry colleagues need to be handled.

As the final point, NZFSA must admit freely and publicly that the processes they used associated with the release of the Swinburn Report, and including their own press releases, have obfuscated the message to the public in relation to Swinburn's message re risk factors associated with A1 and A2 milk. Regardless of the rationale for this obfuscation, and the causes thereof, the obfuscation itself must be admitted.
